Wisconsin Department of Regulation & Licensing

Mail To: **P.O. Box 8935**
Madison, WI 53708-8935
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Madison, WI 53703
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Website: http://www.drl.state.wi.us

PHARMACY SELF-INSPECTION REPORT

APPLICANT NAME: _____

DBA NAME: _____

ADDRESS: _____
_____

TELEPHONE: ( ) _____

HOURS: _____

_____ Change in Ownership*
_____ New Location*
_____ Remodeled**
_____ Reinspection
*(Proposed opening date)
**(proposed remodel start date)

PERSONNEL (Indicate full or part-time for each pharmacist listed.)

Managing Pharmacist: _____ R#: _____
Other Pharmacist(s): _____ R#: _____
_____ R#: _____

Date Compliance Date (actual or anticipated in no event later than opening date)

_____ 1. Pharmacy Label (contains all required information)
_____ 2. Professional service area _____ **Sq.** Ft.
_____ 3. Professional service area where Pharmacist is absent. See Phar 6.04(3)
_____ 4. RX counter surface area _____
_____ 5. Sink
_____ 6. Hot and cold running water
_____ 7. Suitable soap or detergent
_____ 8. Disposal container for waste
_____ 9. Secure narcotic storage or dispersed throughout stock
_____ 10. Centrally monitored alarm system
_____ 11. Operational refrigerator
_____ 12. Sufficient storage space
_____ 13. Proper storage of exempted narcotic preparations & poisons
_____ 14. Electronic balance having sensitivity consistent with Phar 6.06(1a)
_____ 15. Equipment of appropriate design and size for intended pharmacy practice and compounding
_____ 16. Supply of glass metric graduates - 5 ml. to 100 ml.
_____ 17. Supply of wedgewood and glass mortars and pestles
_____ 18. Spatulas - ____ supply of stainless steel ____ 1 non-metallic
_____ 19. Funnels
_____ 20. Heating apparatus
_____ 21. Exempt Narcotic Register - Schedule V
_____ 22. Poison Register
_____ 23. Current certificates posted
_____ 24. a) Prescription files, sec. 450.11(2), Stats.
b) Controlled Substance RX Files, Wis. Admin. Code, sec. Phar 8.03(2)
c) Medication profile, Wis. Admin. Code, sec. Phar 7.07

AFFIDAVIT OF APPLICANT

The undersigned, having been duly sworn on oath, states that the facts and statements herein contained are true and correct based upon personal knowledge of the undersigned.

_____ _____
Managing Pharmacist Signature Date

Subscribed and sworn before me this _____ day of _____, 20 __

by _____

SEAL

_____
Notary Public, State of Wisconsin
My commission expires: _____

#923 (Rev. 10102)
Ch. 450, Stats.

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PHARMACY EXAMINING BOARD

PHARMACY SELF-INSPECTION
Information requested is required for processing

It is recommended that pharmacies use the Wisconsin Statutes and Administrative Code Relating to the Practice of Pharmacy to facilitate this continuing educational and evaluation procedure.

Directions: On the line next to the requirement, please complete each line indicating the date of compliance, either actual or anticipated, but in no event later than the proposed opening date indicated on the cover page of Form #923, or "NA" for not applicable. If answered "NA" please describe why this rule does not apply to your specific pharmacy on an attached document. For clarity, please write down the corresponding item number (listed on the left hand side of each requirement) for each description you write on the attached Self-Inspection Notes.

CHAPTER PHAR 5 WISCONSIN ADMINISTRATIVE CODE (LICENSE RENEWAL)

PHAR 5.03 Display of licenses.

1. _____ Each pharmacist's license is displayed in public view. (Pharmacists need only display license at primary site of employment.) The current renewal card (and no other visible renewal card) is displayed with the license.
2. _____ The pharmacy license and current renewal are on public display. Ch. 450.09(5), Stats.

PHAR 5.04 Renewal prohibited; relicensure.

3. _____ A pharmacist whose license is currently suspended or revoked may not renew their license unless it has been reinstated by the board and they are otherwise qualified for renewal.

PHAR 5.05 Requirements for late renewal; reinstatement.

4. _____ A pharmacist who files an application for renewal of a license within 5 years after renewal date must file the following with the board:
   (a) The DRL's application for renewal.
   (b) The fee required under s. 440.08(2), Stats., plus the late fee required under s. 440.08(3), Stats.
5. _____ A pharmacist who files an application for renewal of a license 5 years or more after the renewal date must file with the board the requirements under Phar 5.05(1) and verification of successful completion of examinations and/or educational requirements, required by the board.

CHAPTER PHAR 6 WISCONSIN ADMINISTRATIVE CODE

PHAR 6.03 Changes in managing pharmacist.

6. _____ Any change in managing pharmacist has been reported to the Pharmacy Examining Board. (This section requires notification within 5 days of the date of change.) (The Pharmacy Examining Board strongly suggests completion of this Pharmacy Self-Inspection by any new managing pharmacist.)

PHAR 6.04 Floor design.

7. _____ Professional service area has a minimum of 250 sq. ft. (20% limit on space used for storage of bulk pharmaceuticals)
8. _____ (If not, has variance been approved by the Pharmacy Examining Board)
9. _____ Prescription counter is at least 12 sq. ft. of free working area for compounding and dispensing and at least 18 inches wide (Space for records, computer and supplies not included.)
10. _____ Professional service area secure where pharmacist is absent. If R.Ph. always present, enter "N/A" in item 9 , skip items 10 to 17 .
11. _____ The pharmacy can convert to a non-prescription or sundry outlet without a pharmacist present if:
12. _____ 1. Present barrier has been approved by the Pharmacy Examining Board
13. _____ 2. Barrier is locked in the absence of the pharmacist.
14. _____ 3. Telephone restrictions are observed
15. _____ 4. Signs are posted at the entrance to the building and the professional service area displaying the hours the pharmacist will be on duty.

16. _____ 5. The manner in which the telephone is answered does not imply that the location is, at that time, operating as a pharmacy. Note; Pharmacy services are not provided: including no prescription being picked up. [Phar 7.01(e)].
17. _____ 6. Pharmacy Examining Board has been notified of the hours the establishment will be operated as a sundry outlet.
18. _____ 7. The managing pharmacist is responsible for compliance with all professional service area security requirements.
19. _____ Modifications to the floor plan have been filed with the board if remodeling has occurred.

PHAR 6.05 [Ch. 450.09(4), Stats.] Sanitation.

20. _____ Pharmacy is maintained in a clean and orderly manner.
21. _____ Suitable sink supplied with hot and cold running water, detergent and adequate waste disposal container are provided.

PHAR 6.06 Equipment.

22. _____ The professional service area of a pharmacy has equipment of appropriate design and size for the intended pharmacy practice consisting of at least the following equipment:
23. _____ An electronic balance that has a sensitivity of 1 milligram, or a mechanical torsion prescription balance that has a sensitivity reciprocal of 6 milligrams.
24. _____ One set of accurate weights appropriate for any mechanical torsion prescription balance being used for the purpose of compounding.
25. _____ A supply of transparent glass graduates in single metric scale capable of measuring 5 to 100 mls.
26. _____ An accurate device to measure less than 5 ml. (syringe acceptable).
27. _____ Supply of Wedgewood and glass mortars and pestles.
28. _____ Supply of stainless steel spatulas and one hard rubber spatula.
29. _____ Supply of acid, base and solvent resistant funnels.
30. _____ Heating device for compounding (hot plate, microwave oven, etc.).
31. _____ Ointment slab or ointment paper.
32. _____ Latest available or immediately accessible version of federal and state pharmacy laws consisting of:
    1. DEA Regulations, 21 CFR 1300 to End: www.access.gpo.gov/nara/cfr/cfr-table-search.html
    2. Wisconsin pharmacy laws (Ch. 450 Statutes): www.legis.state.wi.us/rsb/statutes.html
    3. Wisconsin Controlled Substances Act (Ch. 961 Statutes): www.legis.state.wi.us/rsb/statutes.html
    4. Wisconsin Administrative Code (Rules of the Pharmacy Examining Board): www.legis.state.wi.us/rsb/code/phar/phar.html

    Note: Statutes and rules may be made available via electronic means with immediate accessibility to satisfy this portion of the rule.
33. _____ References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions, patient counseling, compounding and pharmaceutical calculations and generic substitution.
34. _____ Telephone number of a poison center (conspicuously posted in the professional service area).

Note: Procedure for variance of minimum equipment is found in Phar 6.06(k)(2).

PHAR 6.07 Storage.

35. _____ Refrigerator adequate for biologicals and other drugs.
36. _____ Sufficient shelf, drawer or cabinet space.
37. _____ Controlled substances are stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory in a manner that obstructs theft. (Alphabetical storage on open shelves of highly sought after controlled substances is not considered adequate.)

PHAR 6.08 Security.

38. _____ The Pharmacy has a centrally monitored alarm system in the pharmacy or the immediate physical structure within which the pharmacy is located.
39. _____ PHAR 1.02(14) Hypodermic needles and syringes, poisons and Schedule V controlled substances are only in the professional service area.

State of Wisconsin Department of Regulation & Licensing

CHAPTER PHAR 7 WISCONSIN ADMINISTRATIVE CODE

Phar 7.01 Minimum procedures for compounding and dispensing.

(1) Only licensed pharmacists (or interns under supervision),

40. _____ (a) Reviews all original and renewal prescription orders, whether electronic, written or oral; and determines therapeutic compatibility and legality of the prescription order. The review shall include, when indicated or appropriate, consultation with the prescriber. (See PHAR 7.07(4) for responsibility to review profile.)

41. _____ Ch. 450.13(1), Stats. Inform the patient of drug produce equivalent options.

Note: Ch. 450.13(5), Stats. amended in 1992 exempts hospitals with formularies for inpatients only.

42. _____ (b) Read and interpret a prescriber's directions for use for the purpose of accurately transferring instructions to the prescription label.

43. _____ (c) If an agent of the pharmacist procures, measures or counts prefabricated dosage forms or compounds, mixes and combines ingredients the pharmacist verifies accuracy of the agent's actions. (Agent of a pharmacist is allowed to compound, mix and combine ingredients with a specific written protocol and pharmacist verification as stated in Phar 7.015(j).

44. _____ (d) Make a final check on the accuracy and correctness of the prescription and identify the pharmacist responsible for the original or renewed prescription.

45. _____ (e) Give the patient or agent appropriate consultation relative to the prescription, except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a patient's residence, is not satisfied by only offering to provide consultation.

46. _____ (em) Transfer the prescription to the patient or agent of the patient.

47. _____ (f) Receive, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on reverse side of the prescription order, medication profile record, or uniformly maintained and readily retrievable document, the following information.

1. Date renewed.
2. Name of practitioner authorizing renewal if different from original prescriber.
3. Quantity of drug dispensed.
4. Pharmacist renewing the prescription.

48 _____ (2) Subsection (1)(d) and (e) does not prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug delivery systems. Sub (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharge patients.

49. _____ (3) Each pharmacist's supervision of compounding and dispensing activities as defined in (1)(c) is limited to one pharmacist intern and four pharmacy technicians at any time.

Note: Any higher ratio *must* be approved by the Pharmacy Examining Board.

PHAR 7.015 Pharmacy technician; defining roles/duties.

50. _____ (1) The pharmacy technician is a non-pharmacist or non-pharmacist intern who, under the general supervision of a pharmacist, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescription orders and inventory management.

Note: Pharmacy technician does not include ancillary persons, which includes: clerks, secretaries, cashiers, or delivery persons who may be present in the pharmacy, unless they are performing technical functions as delineated in Phar 7.015(2), in which case they are a technician when performing these functions.

51. _____ (2) The pharmacist delegates technical dispensing functions to a pharmacy technician, but only under the general supervision of the pharmacist where the delegated functions are performed. Technical dispensing functions include:

52. _____ (a) Accepting written or electronic prescription orders from the prescribing practitioner or from the prescribing practitioner's agent.

53. _____ (b) Accepting original oral prescription orders from the prescribing practitioner or their agent, if the conversation is recorded and listened to and verified by the pharmacist prior to dispensing.

54. _____ (c) Requesting authorization for a refill from the prescribing practitioner.

55. _____ (d) Accepting oral authorization for a refill from the prescribing practitioner or their agent, provided there are no changes to the original prescription order.

56. _____ (e) Accepting a request from a patient to refill a prescription.
57. _____ (f) Obtaining and entering patient or prescription data into the patient information system.
58. _____ (g) Preparing a prescription label.
59. _____ (h) Retrieving medication from stock, counting or measuring medication and placing the medication in its final container.
60. _____ (i) Reconstituting prefabricated dosage forms.
61. _____ (j) Compounding pharmaceuticals pursuant to written policies and procedures on file in the pharmacy at the time of compounding.
62. _____ (k) Affixing a prescription label to its final container.
63. _____ (l) Placing ancillary information on the prescription label.
64. _____ (m) Prepackaging and labeling drugs for dispensing by a pharmacist.
65. _____ (n) Preparing unit dose carts for final review by a pharmacist.
66. _____ (o) Retrieving and transporting stock medication to and from pharmacist approved areas.
67. _____ (p) Other technical functions that do not require the professional judgment of a pharmacist.

(3) The pharmacy technician may not do any of the following:

68. _____ (a) Provide the final verification for the accuracy, validity, completeness or appropriateness of a filled prescription or medication order.
69. _____ (b) Perform any of the following tasks: participation in final DURs; make independent therapeutic alternate drug selections, participation in final drug regimen screening; perform any act necessary to be a managing pharmacist, or administer any prescribed drug products, devices or vaccines.
70. _____ (c) Provide patient counseling, consultation exercise or patient specific judgment.
71. _____ (d) Transfer the prescription to the patient or agent of the patient.
72. _____ (4) The pharmacist provides the final verification for the accuracy, validity, completeness and appropriateness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative.

PHAR 7.02 Prescription label; name of drug product dispensed.

73. _____ The prescription label discloses brand name and strength or generic name, strength and manufacturer or distributor of the drug or drug product dispensed...unless prescriber requests omission.

PHAR 7.03 Prescription renewal limitations.

74. _____ Prescription orders for any drug other than a controlled substance bearing renewal authorization "prn" are limited to a period of one year from the date of original order.
75. _____ All renewal authorizations are void when the patient-physician relationship has ceased (includes death or retirement of prescriber).

PHAR 7.04 Return or exchange of health items.

76. _____ (1) (a) "Health items" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicine, or items of personal hygiene.
77. _____ (b) "Inpatient health care facility" means any hospital, nursing home, county homes, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities.
78. _____ (2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned, except for any of the following:
79. _____ (a) No health items from an inpatient health care facility if they are in their original container and are judged not to be adulterated or misbranded.
80. _____ (b) Where the health items were dispensed in error, were defective, adulterated, misbranded or dispensed beyond their expiration date.
81. _____ (c) If the pharmacist deems harm would result to the public or patient if left in the possession of the patient, agent or others.
82. _____ (3) Health items returned to the pharmacy under (b) and (c) are not sold, resold, repackaged, given away or otherwise distributed. They must be destroyed or sent for destruction.
83. _____ (4) It is not a return for a patient's medication to be delivered to the pharmacy for repackaging and relabeling of previously dispensed medication, and subsequent return to the patient.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

PHAR 7.05 Prescription records.

84. _____ (1) Records of prescriptions dispensed are maintained for 5 years after the date of last renewal.
85. _____ (2) All systems used for maintaining a record of any prescription include: patient identification, name, strength, and dosage form of produce dispensed, quantity, dates of all instances dispensed; practitioner identification, pharmacist identification, and retrieval designation.

Note: All systems must comply regardless of implementation date.

86. _____ (3) (a) Transfer of original prescription order information on a non-controlled drug prescription may occur between pharmacies on an unlimited basis.
87. _____ (b) A prescription for a controlled substance may only be transferred between two pharmacies one time.

Note: common file exception in (5) below.

88. _____ (c) Transfer communicated directly between two pharmacists.
89. _____ (d) Pharmacist making the transfer records the word "VOID" on the face of the invalidated prescription order, and on the back, the name and address of the pharmacy to which transferred, name of pharmacist receiving order, and the date and name of the pharmacist transferring the information.
90. _____ (e) The pharmacist receiving the transferred prescription information records in writing: the word "TRANSFER," the date of issuance of the original prescription order, original number of renewals authorized on the original prescription order, the date of original dispensing, number of valid renewals remaining and the date of the last renewal, the transferring pharmacy's name, address and their original Rx number, and name of pharmacist making transfer.
91. _____ (4) Written copies of prescription orders provided by the pharmacist are identified as "COPY – FOR INFORMATION ONLY". Prescribed drugs are not dispensed based on information copies.
92. _____ (5) Pharmacies having access to a common central processing unit are not limited in the transfer of original Rx order for the purpose of renewal if:
93. _____ (a) Prior approval received from the PEB.
94. _____ (6) If a computerized system is utilized for maintaining required records, it includes the following features:
95. _____ (a) Capable of producing a printout of any prescription data, which the user pharmacy is responsible for maintaining, and the printout can be received within 48 hours.
96. _____ (b) An auxiliary procedure for prescription dispensing documentation during the periods of down time. The auxiliary procedure ensures that prescription renewals are authorized by the original prescription order and all appropriate data are retained for on-line entry as soon as the computer system is available for use.

PHAR 7.065 Answering machines in pharmacies

97. _____ Oral prescription orders may be received at a pharmacy via telephone answering machine and dispensed by the pharmacist if the voice of the physician or agent is known to the pharmacist and providing other requirements for documenting and filling are met.

PHAR 7.07 Medication profile record system.

Medication profile record system for each patient includes:

98. _____ (1) An individual medication profile record system is maintained for all persons for whom prescriptions, original or renewal are dispensed for outpatient use. The system allows retrieval of the information.
99. _____ (2) The following minimum information is retrievable: patient name, or other identifying information, address of the patient, birth date of the patient if obtainable, name, strength, dosage form, and quantity of the drug product dispensed, directions for use, retrieval designation assigned to the prescription order, practitioner identification, and the date of each dispensing for original and renewal prescriptions.
100. _____ (3) Allergies, adverse drug reactions, drug idiosyncrasies and chronic condition.
101. _____ (4) The pharmacist reviews the profile before dispensing. (See PHAR 7.01(a)).
102. _____ (5) Medication profile records, if used as the only documentation of renewal dispensing, are maintained for not less than 5 years following the last entry. If the profile records are not used as the only documentation of renewal dispensing they are maintained not less than one year past the last entry.

PHAR 7.08 Prescription orders transmitted electronically

Electronic transmission of prescription orders is available in the pharmacy. If not applicable, enter N/A in item 103 and skip to Phar 7.09, item 114

103. _____ (1) (a) Prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device.

104. _____ (b) Prescription orders for schedule II controlled substances may not be transmitted electronically except as emergency orders (Phar 8.09).

(2) In order to dispense a prescription transmitted electronically, the following must be assured by the pharmacist:

105. _____ (a) The transmission is only to the pharmacy of the patient's choice, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.

106. _____ (b) The transmission contains the sender's name and telephone number, the time and date of transmission, and the pharmacy intended to receive the transmission.

107. _____ (c) The transmission is designated "electronically transmitted prescription", or words or abbreviations to that effect.

108. _____ (d) Contains all other information that is required in a prescription order.

109. _____ (3) A secure method of validation such as the prescribing physician's electronic signature, accompanies the electronically transmitted prescription.

110. _____ (4) Any visual or electronic document received electronically are accessible only within the professional service area of the pharmacy (to protect patient confidentiality and assure security).

111. _____ (5) The pharmacist must ensure the security, integrity, and confidentiality of the prescription order. The electronic system has adequate security and system safeguards to prevent and detect unauthorized access, modification, or manipulation of patient records. Any alterations in the drug order are documented including the identification of the pharmacist responsible for the alteration.

112. _____ (6) Password(s), known only by those authorized to use the system, is required to gain access to mail containing prescription orders.

113. _____ (7) The pharmacist does not use any electronic device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying prescription orders or in order to circumvent pharmacy laws.

PHAR 7.09 Automated dispensing systems.

If pharmacy does not use an automated dispensing system (ADS), place "N/A" in item 114 and skip to Phar 7.10, item 133.

114. _____ (1) (a) The ADS performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

115. _____ (2) The ADS may be used in a community pharmacy, as provided in this section.

116. _____ (3) The ADS may be used as provided in this section by an institutional pharmacy serving an inpatient health care facility, that has an established program of receiving prescription orders, and dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. The ADS used by the institutional pharmacy shall only be located in that institutional pharmacy or within the inpatient health care facility.

(4) The managing pharmacist of a community or an institutional pharmacy is responsible for the following:

117. _____ (a) The ADS is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed and complies with record keeping and security safeguards pursuant to sub (5).

118. _____ (b) Implementing an ongoing quality assurance program that monitors performance of the ADS, which is evidenced by written policies and procedures.

119. _____ (c) Providing the board with prior written notice of the installation or removal of an ADS including: name and address of the pharmacy, initial location of the ADS, and identification of the managing pharmacist.

120. _____ (d) Assigning, discontinuing or changing personnel access to the system.

121. _____ (e) Assuring access to the medications complies with state and federal laws.

122. _____ (f) Assuring the ADS is stocked accurately and in accordance with established written policies and procedures.

(5) The ADS complies with the following provisions:

123. _____ (a) The pharmacy maintains on-site documentation including: name and address of the pharmacy or inpatient health care facility where the system is being used, the system manufacturer's name, model and serial number, description of how the system is used, written quality assurance procedures to determine continued appropriate use of the system, and except as required pursuant to par (b), written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

124. _____ (b) All written policies and procedures are maintained in the pharmacy responsible for the ADS.

125. _____ (c) The ADS has adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

126. _____ (d) Records and data kept by the ADS meet the following requirements: all events involving the contents of the ADS are recorded electronically, records are maintained by the pharmacy and are available to the board (including: the time and location of the system accessed, identification of the individual accessing the system, type of transaction, name, strength, dosage form and quantity of the drug accessed; name of the patient for whom the drug was ordered, such additional information as the managing pharmacist may deem necessary.)

127. _____ (e) The stocking of all medications in the ADS is accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an ADS is located within a pharmacy the supervision is direct.

128. _____ (f) A record of medications stocked into the ADS is maintained for 5 years and includes identification of the person stocking and pharmacist checking for accuracy.

129. _____ (g) All containers of medications stored in the ADS are packaged and labeled in accordance with state and federal law.

130. _____ (h) All aspects of handling controlled substances meet the requirements of all state and federal laws.

131. _____ (i) The ADS provides a mechanism for securing and accounting for medications removed from and subsequently returned to the ADS, in accordance with state and federal law.

132. _____ (j) The ADS provides a mechanism for securing and accounting for medication returned to the system and accounting for wasted medications in accordance with state and federal law.

PHAR 7.10 Administration of drug products and devices other than vaccines.

A pharmacist may administer a drug product or device in the course of teaching a patient self-administration technique. Pharmacists administering a prescribed drug product or device by injection must satisfy each of the following:

133. _____ Completed a 12 hour course of study and training, approved by the ACPE or the Board in injection techniques, emergency procedures and record keeping.

134. _____ Maintain at least $1,000,000 in liability insurance for each occurrence, and $2,000,000 for all occurrences in any one policy year, for errors, omissions or neglect in the administration by injection. The pharmacist must maintain proof of this requirement and provide upon request of the board or department.

135. _____ Maintain written procedures regarding the administration by injection of a prescribed drug product or device in the course of teaching self-administration techniques to a patient.

UNIFORM CONTROLLED SUBSTANCES ACT

961.23, Stats. Dispensing of schedule V substances. (Non-legend)

136. _____ (1) Products are sold in good faith as a medicine.
Even without 48 hour violations, pharmacists must be prepared to substantiate the clinical need for frequent sales to the same individual. (Ch. 961.38(4), Stats.)

137. _____ (2) Sold only by the pharmacist.

138. _____ (3) The name and address of the pharmacy is attached to the immediate container.

139. _____ (4) The pharmacist records the name and address of the purchaser, as well as the name and quantity of product sold.

140. _____ If purchaser is unknown to the pharmacist, identification is validated.

141. _____ The pharmacist and the purchaser sign the record.

_____ (5) Sales are restricted :

142. _____ (a) 8 ounces of a produce containing opium.

143. _____ (b) 4 ounces of any other Schedule V substance.

144. _____ (c) 48 hour interval is observed.

State of Wisconsin Department of Regulation & Licensing

CHAPTER PHAR 8 WISCONSIN ADMINISTRATIVE CODE

PHAR 8.02 Records for controlled substances.

145. _____ (1) Records are complete and accurate for each controlled substance received, distributed, dispensed or disposed of in any other manner.

(2) Records required by federal controlled substances act and Ch. 961, Stats., are:

146. _____ (a) Maintained at the pharmacy location where received and dispensed or manufactured.

147. _____ (b) Available for inspection for at least 5 years.

148. _____ (c) Includes a biennial inventory of all Schedule II, III, IV and V substances (readily retrievable). Wisconsin DEA district office, 1000 N. Water St., Suite 1010, Milwaukee, WI 53202, (414-297-3395) provides instructions and forms for destruction of controlled substances.

(3) Records are maintained as follows:

149. _____ (a) Records of Schedule II controlled substances (other than prescription orders) are maintained separately.

150. _____ (b) Records of Schedule III, IV and V controlled substances are separate or are readily retrievable.

151. _____ (c) Executed Schedule II order forms (DEA form 222) completed and kept in the pharmacy.

_____ (d) Records of controlled substances distributed or dispensed include:

152. _____ 1. Name of the substance.

153. _____ 2. Dosage form, strength and quantity.

154. _____ 3. Quantity and date of distribution, as well as name, address and DEA registration number to whom distributed.

155. _____ 4. Number of units, date of receipt, and name, address and DEA registration number from whom received.

156. _____ 5. Name and address to whom dispensed, date, quantity dispensed, and name or initials of pharmacist dispensing.

(e) Records for dispensed Schedule V substances:

157. _____ 1. If dispensed as a prescription, it is filed the same as Schedule III and IV orders.

158. _____ 2. If dispensed other than pursuant to prescription order, the required entry (see 961.23, Stats.) is placed in a bound Schedule V register at the time of transaction.

159. _____ (f) Theft or significant loss of any controlled substance has been reported to the DEA (Milwaukee office), local police, and Pharmacy Examining Board.

PHAR 8.03 Filing prescription orders.

160. _____ Controlled Rx orders are filed chronologically, are readily accessible; and maintained for at least 5 years.

161. _____ Schedule II prescription orders are filed separately or are filed with Schedule III, IV and V orders (which have a one inch red C in the lower right corner).

162. _____ Schedule III, IV and V prescription orders are filed separately or have a one inch red C if filed with non-controlled Rx orders. (Schedule II Rx orders are not filed with non-controlled Rx orders.) The requirement to mark with a red "C" may be waived if the pharmacy has an automated processing system or electronic record keeping that permits identification by prescription order number and retrieval of original documents by prescriber's name, patient name, drug dispensed and date filled.

PHAR 8.04 Purpose of issue of prescription.

163. _____ Pharmacists are aware of their responsibility to dispense for legitimate medical purposes.

164. _____ Controlled substances are not dispensed (pursuant to a prescription order) to a practitioner for the purpose of administration or general dispensing to patients.

165. _____ Controlled substances (Schedule II, III or IV) are not dispensed pursuant to a prescription order to a practitioner for their own personal use. [Ch. 961.38(5), Stats.]

PHAR 8.05 Dispensing controlled substances.

166. _____ (1) Written prescription orders for all controlled substances are dated and signed on the day issued and contain the following:

(a) Full name and address of patient.

(b) Name, address and DEA number of practitioner.

(c) Name, strength, dosage form and quantity of drug prescribed.

(d) Directions for use.

Prescription orders (in ink or typewritten) are signed by the practitioner.

DEA registration of practitioner is validated by pharmacist.

167. _____ (2) The pharmacist initials and dates prescription orders for all controlled substances.
Note: If the party receiving a Schedule II prescription is not personally known to the pharmacist, the printed name, signature and address of that person is recorded on the reverse side of the prescription order.
168. _____ (3) Prescriptions containing Schedule II substances are dispensed pursuant to written prescription orders signed by the practitioner.
169._____ Controlled substance prescriptions must be dispensed within 60 days following the date of issue of the prescription order.
Note: date of receipt on face of Rx order.
170. _____ (4) Prescription orders for controlled substances are not dispensed unless the prescription order contains all of the information required in sub. (1). For any controlled substances prescription order, a pharmacist may not add, modify or clarify the patient's name, drug prescribed, except for generic substitution as permitted by law and the prescribing practitioner's signature. After consultation with the prescribing practitioner, a pharmacist may add, modify or clarify the strength, dosage form, quantity prescribed, date of issuance and directions for use for a schedule II controlled substance prescription order. For a schedule II controlled substance prescription order, a pharmacist may add, modify or clarify the registration number of the practitioner, and the address of the practitioner and the patient if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation with the practitioner. A pharmacist may add, modify or clarify any information allowed in this subsection missing from a prescription order for a Schedule III, IV or V controlled substance that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner. A patient may only provide information to a pharmacist to add, modify or clarify the patient'' address. The prescription order shall be initialed and dated by the pharmacist and shall indicate the addition, modification or clarification of information and the manner by which the pharmacist obtained that information.

PHAR 8.06 Renewing prescriptions for controlled substances.
171. _____ (1) Prescriptions for Schedule II controlled substances are not renewed.
172. _____ (2) The prescribing practitioner may authorize renewals of Schedule III or IV controlled substances on the original prescription order or through an electronic or oral renewal authorization.
173. _____ (a) The pharmacist obtaining an electronic or oral authorization notes the following on the prescription order, medication profile, or document.:
174. _____ 1. Date authorization is received.
175. _____ 2. Quantity of drug authorized.
176. _____ 3. Number of renewals.
177. _____ 4. Identification of practitioner authorizing the renewals if different from the original prescriber.
178. _____ 5. Identification of the pharmacist who received the authorization.
179. _____ (b) The quantity of each renewal authorized is equal to or less than the quantity authorized for the initial dispensing of the original prescription.

180. _____ (3) Renewal of prescriptions for Schedule III and IV substances is limited to:
181. _____ (a) Within 6 months of date of original order.
182. _____ (b) No more than 5 authorized renewals.
183. _____ (4) Prescriptions for Schedule V substances are renewed only as expressly authorized by the practitioner.
Note: The 6-month/5 renewal limitations do not apply to prescription orders for Schedule V substances.

PHAR 8.07 Partial dispensing of controlled substances.
184. _____ (1) Substances in Schedules III, IV and V may be partially dispensed.
185. _____ (2) Partial dispensing of Schedule II substances is permissible: If pharmacist unable to supply full quantity ordered. Remaining portion may be dispensed within 72 hours of the first partial dispensing (or prescriber notified).
--No further quantity dispensed after 72 hours. A new prescription order will be required.
186. _____ (3) Partial dispensing of Schedule II substances is permissible if patient is in long term care facility (LTCF), or has a medical diagnosis documenting a "terminal illness". Valid for 60-day period.
Pharmacist enters each partial dispensing. Enter "LTCF" or "terminal illness" on prescription.
187. _____ (4) Information pertaining to current prescription orders for Schedule II controlled substances for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

188. _____ (a) Display or printout of: the original prescription order designation, date of issue, identification of prescribing practitioner, identification of patient, name and address of the LTCF or name of address of the hospital or residence of the patient, identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3).

189. _____ (b) Immediate updating of the prescription order record each time there is partial dispensing of the prescription.

190. _____ (c) Retrieval of partially dispensed Schedule II prescription information identical to that required by s. Phar 7.05(2) for all prescription renewal information.

PHAR 8.08 Labeling prescriptions containing controlled substances.

191. _____ The prescription label for controlled substances includes: Date dispensed, pharmacy name and address, Rx number; full name of patient; name of the practitioner; directions for use; and appropriate cautionary statements.

PHAR 8.09 Emergency dispensing of Schedule II substances.

(1) The pharmacists understand the criteria for "emergency" to mean that the practitioner has determined that:

192. _____ (a) Immediate administration of the CS II substance is necessary.

193. _____ (b) No appropriate alternative, including non-Schedule II substance.

194. _____ (c) Not possible to provide written order prior to dispensing.

Note: It is important for pharmacists to be aware that the "emergency" procedure should not be used for routine dispensing of Schedule II substances.

(2) In an emergency when the pharmacist dispenses a Schedule II substance with an electronic or oral authorization:

195. _____ (a) The quantity prescribed and dispensed is limited to the amount adequate for the emergency situation.

196. _____ (b) The Rx order is immediately reduced to writing by the pharmacist, including all information listed in Phar 8.05 except the signature of the practitioner.

197. _____ (3) If the practitioner is not known to the pharmacist, reasonable effort is made to authenticate the prescriber.

198. _____ (4) The pharmacist assures receipt of a written order within 7 days after the authorized emergency dispensing (or it is postmarked within 7 days). The written order will include:

199. _____ (a) "authorization for emergency dispensing" on the front.

200. _____ (b) date of the electronic or oral order.

201. _____ Upon receipt, the pharmacist attaches the written order to the oral emergency prescription order.

202. _____ If the practitioner fails to deliver the written order, the Department of Regulation and Licensing is notified.
(Failure to provide this notification voids the authority to dispense emergency orders.)

PHAR 8.11 Controlled substances in emergency kits for long term care facilities.

If you do not service a LTCF, place "N/A" in item 203 and skip to Phar 8.12, item 208.

Long term care facilities, which are not registered with the DEA, meet the following requirements regarding emergency kits containing controlled substances:

203. _____ (1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.

204. _____ (2) The pharmaceutical services committee of the facility have security safeguards for each emergency kit stored in the LTCF, which include the designation of the individuals who may have access to the kits and a specific limitation on the type and quantity of controlled substances permitted to be placed in each emergency kit.

205. _____ (3) A pharmacist is responsible for control and accountability for kits within the LTCF, which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.

206. _____ (4) The pharmaceutical services committee established the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF, which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

207. _____ (5) The pharmacist is aware that noncompliance with these rules may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

PHAR 8.12 Facsimile Transmission.

208. _____ (1) A pharmacist may dispense a prescription, other than a Schedule II based on a fax prescription from a practitioner or their agent.

209. _____ (a) It shall contain all the information of a valid written prescription as well as the date and time of transmission and the telephone number and name of the transmitter.

210. _____ (b) If fading paper, it must be copied and attached to the copy received.
211. _____ (2) Schedule II prescriptions may be received if all the requirements of section (1) are met and any of the following:
212. _____ (a) The prescription is to be compounded for the direct parenteral, intravenous, intra muscular, subcutaneous or intra spinal infusion to a patient.
213. _____ (b) The patient resides in a long term care facility.
214. _____ (c) The patient is enrolled in a hospice certified by Medicare under title XVIII or licensed by this state.
215. _____ (3) A prescription order transmitted by facsimile shall be considered the original written prescription order.

CHAPTER PHAR 10 WISCONSIN ADMINISTRATIVE CODE (STANDARDS OF PROFESSIONAL CONDUCT)

216. _____ All pharmacists at this pharmacy are aware of the specific practices enumerated in Phar 10.03.
217. _____ The pharmacist avoids dispensing or causing to be dispensed a drug which is outdated or contaminated or known by the pharmacist to be unsafe for consumption.
Note: (While it is not the objective of this self-inspection project to enumerate conduct considered unprofessional, as listed in Phar 10, there is a need to identify problems created when a pharmacy's inventory includes examples of long-outdated and/or unacceptable numbers of outdated pharmaceuticals and chemicals. Reasonable effort should be demonstrated to remove such items from regular inventory and expedite their return or destruction. In the opinion of the Pharmacy Examining Board, antique containers and display pieces containing crude drugs are not viewed as violations. But good faith requires the removal of chemicals (undated or outdated) from containers in the professional service area unless they are conspicuously set apart in display containers.
218. _____ Pharmacists are required to report to the board any information that reasonably suggests there is a probability that a prescription drug or device dispensed by a pharmacist has caused or contributed to substantial bodily injury or death of a patient.

CHAPTER PHAR 15 WISCONSIN ADMINISTRATIVE CODE (STERILE PHARMACEUTICALS)

These rules apply to pharmacies engaged in the preparation of sterile pharmaceuticals. If pharmacy does not compound sterile pharmaceuticals, please place "NA" in item 219 and skip to Phar 16, item 263.

PHAR 15.03 Policy and procedure manual

219. _____ Pharmacy prepares and maintains a policy and procedure manual for compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceuticals.
220. _____ The manual includes a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, guidelines regarding patient education and provision of pharmaceutical services and up-to-date information on preparation of sterile pharmaceuticals.
221. _____ The policy and procedure manual is available to all personnel and updated annually or as needed to reflect current practice.
222. _____ The policy and procedure manual is available for inspection by the board or its designee.

PHAR 15.04 Physical requirements

223. _____ (1) The pharmacy has a structurally isolated area designated for preparation and documentation associated with sterile pharmaceuticals. Entry and access is restricted to designated personnel to avoid traffic and airflow disturbances. The designated area is of sufficient size to accommodate a laminar airflow hood and proper storage of drugs and supplies.
(2) Environment maintains:
224. _____ (a) A class 100 environment during the normal activity in the workplace where critical objects are exposed and critical activities are performed.
225. _____ (b) Appropriate disposal containers as required by OSHA in 29 CFR Part 1910 for timely disposal of needles, syringes, infectious and cytotoxic wastes.
226. _____ (c) Appropriate environmental controls, including a class II biological safety cabinet if cytotoxic drug products are prepared.
227. _____ (d) Temperature-controlled delivery containers as necessary.
228. _____ (e) For hand washing, a sink with hot and cold running water in close proximity.
229. _____ (f) Administration devices, if necessary.
230. _____ (3) Sufficient reference materials related to sterile pharmaceuticals are available.
231. _____ (4) The designated area is closed and disinfected regularly with appropriate agents.

PHAR 15.05 Records and Reports

232. _____ (1) Maintains records and reports of:
233. _____ (a) Training and competency evaluations of personnel.
234. _____ (b) Documentation of refrigerator and freezer temperatures.
235. _____ (c) Certification of laminar flow hoods.
236. _____ (2) Minimal labeling requirements for sterile pharmaceuticals prepared for a single patient if the pharmaceuticals are to be completely administered within 28 hours:
237. _____ (a) The identity of all solutions and ingredients and their corresponding amounts, concentration or volumes on the final preparation container in such a manner as to allow the locating of problematic final products.
238. _____ (b) The identity of personnel involved in preparation.
239. _____ (c) The date and time of pharmacy preparation where applicable.
240. _____ (d) The final sterile pharmaceuticals expiration date and storage requirements, where applicable.

PHAR 15.06 Delivery of service

241. _____ The pharmacist assures the appropriate environmental control of all products shipped.

PHAR 15.07 Emergency kits

242. _____ When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy supplies the patient or the patient's agent with emergency drugs, when authorized by the physician under protocol, if an emergency situation has been anticipated by either the physician, nurse or pharmacist.
243. _____ The pharmacy provides written instructions on the storage and record keeping requirements for the emergency kit.

PHAR 15.08 Cytotoxic drugs

If pharmacy does not compound cytotoxic drugs, place "NA" in item 244 and skip to Phar 15.09, item 250.

244. _____ All cytotoxic drugs are compounded in a vertical flow, class II biological safety cabinet. If non-exposed surfaces become contaminated with cytotoxic drugs, no products other than cytotoxic drugs are compounded in this cabinet until the cabinet is decontaminated utilizing appropriate techniques
245. _____ Personnel are protected by a protective barrier or apparel which includes gloves, gowns and other applicable protective apparel as described in 29 CFR PART 1910 of OSHA regulations.
246. _____ Appropriate safety and containment techniques for compounding cytotoxics are used in conjunction with aseptic techniques required for preparation of sterile pharmaceuticals.
247. _____ Pharmacy disposal and patient and caregiver education regarding disposal of cytotoxic waste complies with all applicable local, state, and federal requirements.
248. _____ Written procedures for the handling of both major and minor spills of cytotoxic drugs are included in the pharmacy policy and procedure manual.
249. _____ Prepared doses of cytotoxic drugs are dispensed, labeled with proper precautions on the primary and shipping container and are shipped in a manner that minimizes the risk of accidental rupture of the primary container.

PHAR 15.09 Labeling

In addition to the labeling requirements of s. 450.11(4), Stats.

250. _____ Control or lot number.
251. _____ Expiration date and time, when applicable
252. _____ Appropriate auxiliary labeling, including precautions.
253. _____ Storage requirements.
254. _____ Identification of the responsible pharmacist

PHAR 15.10 Patient training

255. _____ A Pharmacist is responsible for documenting the patient's training and competency in managing the type of therapy provided by the pharmacist to the patient if administered by the patient or a caregiver. Pharmacists are responsible for the provision or supervision of the patient training process in any area that relates to compounding, administration, labeling, storage, stability, or incompatibility. A pharmacist is responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

PHAR 15.11 Quality Assurance

256. _____ There is a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.

257. _____ The area designated in Phar 15.04 (2)(a) for preparing sterile pharmaceuticals is certified by an independent contractor. Certification takes place before initial use or after relocation and at least annually.
258. _____ The pharmacy has written procedures requiring sampling for microbial contamination through a validation procedure, simulation of actual aseptic preparation, and by using bacterial growth medium to culture environmental samples.
259. _____ If compounding of parenteral solutions is performed using non-sterile chemicals, extensive end-product sterility testing is documented. Quarantine procedures shall be developed if there is a test failure.
260. _____ A pharmacy has written justification of the assigned expiration date for pharmacy prepared sterile pharmaceuticals.
261. _____ A pharmacy has documentation of quality assurance audits, including infection control and sterile technique audits at least annually.
262. _____ A pharmacy has procedures to assure consistent preparation of sterile pharmaceuticals.

CHAPTER PHAR 16 WISCONSIN ADMINISTRATIVE CODE (CONTINUING EDUCATION)

PHAR 16.02 Continuing education required; waiver

263. _____ (1) At the time of making application for renewal of a license: Each pharmacist required to complete the continuing education requirement provided under s. 450.085, Stats. shall:
264. _____ (a) Sign a statement on the application for renewal certifying that the pharmacist has completed at least 30 hours of acceptable continuing education programs within the 2-year period immediately proceeding the date of his or her application for renewal. (This subsection does not apply to an application for renewal of a license that expires on the first renewal date after the date on which the board initially granted the license.)

Note: The PEB will grant 15 hours of continuing education credit for every one credit of academic training received in coursework which leads to a degree granted by an ACPE approved school of pharmacy.

265. _____ (2) A pharmacist may apply to the board for waiver of the requirements of this chapter on grounds of exceptional circumstances such as prolonged illness, disability or other similar circumstances that the pharmacist indicates have prevented him or her from meeting the requirements. The board will consider each application for waiver individually on its merits.

PHAR 16.03 Acceptable continuing educational programs

266. _____ The educational programs used for CE are approved by the American Council on Pharmaceutical Education (ACPE) at the time of the pharmacist's attendance or other board approved programs. To date the board has only approved ACPE as a provider.

PHAR 16.04 Evidence of compliance

267. _____ The board accepts as evidence of compliance with this chapter certification by a providing institution or organization that a pharmacist has attended and completed approved continuing education programs. Certification may be the original, or verified copies of, documents certifying attendance and completion.

PHAR 16.05 Retention requirement

268. _____ The pharmacist shall retain evidence of compliance for 3 years following the renewal date for the biennium for which 30 hours of credit are required for renewal of a license.

PHAR 16.06 Audit

269. _____ The board may require any pharmacist to submit his or her evidence of compliance with the continuing education requirements to audit compliance.

In the space provided below, for each item that received "NA" following your inspection, indicate why this rule does not apply to your pharmacy. (Attach additional pages if necessary.)

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